

Appl. No. 09/774,555  
Atty. Docket No. 7998  
Amdt. Dated 11/13/2003  
Reply to Office Action of 03/05/2003  
Customer No. 27752

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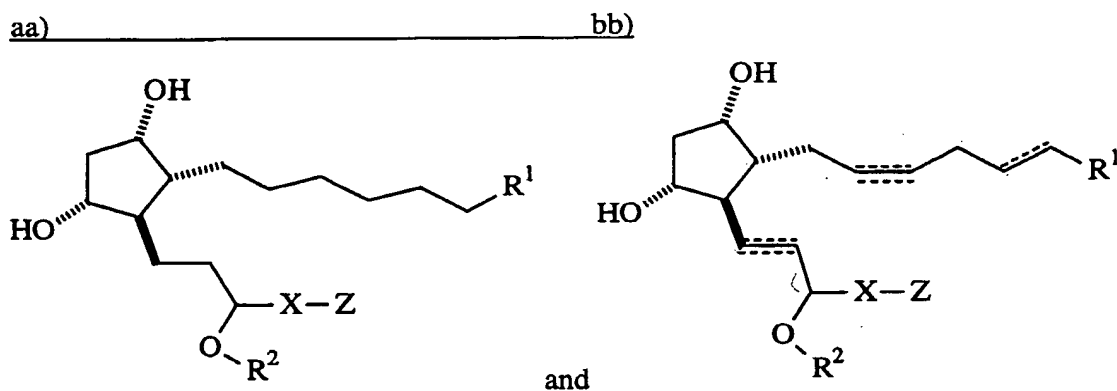
### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

#### Listing of Claims:

1. (Currently Amended) A composition for treating hair loss comprising:

A) an active ingredient selected from the group consisting of a prostaglandin F analog having a structure selected from the group consisting of



pharmaceutically acceptable salts and hydrates of the structures above; biohydrolyzable amides, esters, and imides of the structures above; optical isomers, diastereomers, and enantiomers of the structures above; and combinations thereof;

wherein  $R^1$  is selected from the group consisting of  $C(O)OH$ ,  $C(O)NHOH$ ,  $C(O)OR^3$ ,  $CH_2OH$ ,  $S(O)_2R^3$ ,  $C(O)NHR^3$ ,  $C(O)NHS(O)_2R^4$ , tetrazole, a cationic salt moiety, a pharmaceutically acceptable amine or ester comprising 2 to 13 carbon atoms, and a biometabolizable amine or ester comprising 2 to 13 atoms;

$R^2$  is selected from the group consisting of a hydrogen atom, a lower heterogenous group, and a lower monovalent hydrocarbon group;

$R^3$  is selected from the group consisting of a monovalent hydrocarbon group, a heterogeneous group, a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted monovalent hydrocarbon group, a substituted heterogeneous group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

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$R^4$  is selected from the group consisting of a monovalent hydrocarbon group, a heterogeneous group, a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted monovalent hydrocarbon group, a substituted heterogeneous group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

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X is selected from the group consisting of  $-C\equiv C-$ , a covalent bond,  $-CH=CH-$ ,  $-CH=CH-$ ,  $-CH=N-$ ,  $-C(O)-$ ,  $-C(O)Y-$ ,  $-(CH_2)_n-$ , wherein n is 2 to 4,  ~~$-CH_2NH-$ ,  $-CH_2S-$~~ , and  $-CH_2O-$ ;

Y is selected from the group consisting of an oxygen atom, a sulfur atom, and NH; and

Z is selected from the group consisting of a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group; and

B) a carrier

with the proviso that the bond between carbons five and six of structure bb) cannot be a double bond.

2. (Original) The composition of claim 1, wherein  $R^1$  is selected from the group consisting of  $CO_2H$ ,  $C(O)NHOH$ ,  $CO_2R^3$ ,  $C(O)NHS(O)_2R^4$ , and tetrazole.

3. (Original) The composition of claim 1, wherein  $R^2$  is a hydrogen atom.

4. (Original) The composition of claim 1, wherein  $R^3$  is selected from the group consisting of methyl, ethyl, and isopropyl.

5. (Withdrawn) The composition of claim 1, wherein  $R^4$  is a phenyl group.

6. (Withdrawn) The composition of claim 1, wherein X is a covalent bond and Z is selected from the group consisting of an aromatic ring, a heteroaromatic ring, a substituted aromatic ring, and a substituted heteroaromatic ring.

7. (Withdrawn) The composition of claim 1, wherein X is  $-C\equiv C-$ , and Z is a monocyclic aromatic ring.

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8. (Original) The composition of claim 1, wherein component A) is added in an amount of

$IC_{50} \times 10^{-2} \geq \% \text{ of component A) } \geq IC_{50} \times 10^{-3}$ ,

where  $IC_{50}$  of component A) is expressed in nanomolar units.

B' Contd  
9. (Original) The composition of claim 8, wherein component C) an activity enhancer is added to the composition in an amount of 1 to 20%, and a sufficient amount of component B) is added such that the amounts of components A), B), and C) combined equal 100%.

10. (Original) The composition of claim 1, wherein component B) comprises an ingredient selected from the group consisting of q) an emollient, r) a propellant, s) a solvent, t) a humectant, u) a thickener, v) a powder, w) a fragrance, water, alcohols, aloe vera gel, allantoin, glycerin, vitamin A and E oils, mineral oil, propylene glycol, polypropylene glycol-2 myristyl propionate, dimethyl isosorbide, and combinations thereof.

11. (Original) The composition of claim 10, wherein ingredient q) is selected from the group consisting of stearyl alcohol, glyceryl monoricinoleate, glyceryl monostearate, propane-1,2-diol, butane-1,3-diol, mink oil, cetyl alcohol, isopropyl isostearate, stearic acid, isobutyl palmitate, isocetyl stearate, oleyl alcohol, isopropyl laurate, hexyl laurate, decyl oleate, octadecan-2-ol, isocetyl alcohol, cetyl palmitate, di-n-butyl sebacate, isopropyl myristate, isopropyl palmitate, isopropyl stearate, butyl stearate, polyethylene glycol, triethylene glycol, lanolin, sesame oil, coconut oil, arachis oil, castor oil, acetylated lanolin alcohols, petrolatum, mineral oil, butyl myristate, isostearic acid, palmitic acid, isopropyl linoleate, lauryl lactate, myristyl lactate, decyl oleate, myristyl myristate, polydimethylsiloxane, and combinations thereof.

12. (Original) The composition of claim 10, wherein ingredient r) is selected from the group consisting of propane, butane, isobutane, dimethyl ether, carbon dioxide, nitrous oxide, and combinations thereof.

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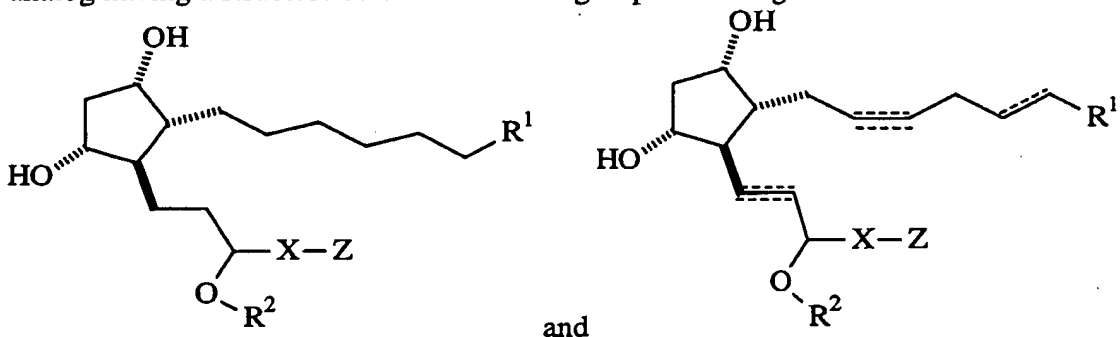
13. (Original) The composition of claim 10, wherein ingredient s) is selected from the group consisting of water, ethyl alcohol, methylene chloride, isopropanol, castor oil, ethylene glycol monoethyl ether, diethylene glycol monobutyl ether, diethylene glycol monoethyl ether, dimethyl sulfoxide, dimethyl formamide, tetrahydrofuran, and combinations thereof.

14. (Original) The composition of claim 10, wherein ingredient t) is selected from the group consisting of glycerin, sorbitol, sodium 2-pyrrolidone-5-carboxylate, soluble collagen, dibutyl phthalate, gelatin, and combinations thereof.

15. (Original) The composition of claim 10, wherein ingredient v) is selected from the group consisting of chalk, talc, fullers earth, kaolin, starch, gums, colloidal silicon dioxide, sodium polyacrylate, tetra alkyl ammonium smectites, trialkyl aryl ammonium smectites, chemically modified magnesium aluminum silicate, organically modified montmorillonite clay, hydrated aluminum silicate, fumed silica, carboxyvinyl polymer, sodium carboxymethyl cellulose, ethylene glycol monostearate, and combinations thereof.

16. (Withdrawn) A method of treating hair loss comprising administering to a mammal a composition comprising:

A) an active ingredient selected from the group consisting of a prostaglandin F analog having a structure selected from the group consisting of



pharmaceutically acceptable salts and hydrates of the structures above; biohydrolyzable amides, esters, and imides of the structures above; optical isomers, diastereomers, and enantiomers of the structures above; and combinations thereof;

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wherein  $R^1$  is selected from the group consisting of  $C(O)OH$ ,  $C(O)NHOH$ ,  $C(O)OR^3$ ,  $CH_2OH$ ,  $S(O)_2R^3$ ,  $C(O)NHR^3$ ,  $C(O)NHS(O)_2R^4$ , tetrazole, a cationic salt moiety, a pharmaceutically acceptable amine or ester comprising 2 to 13 carbon atoms, and a biometabolizable amine or ester comprising 2 to 13 atoms;

$R^2$  is selected from the group consisting of a hydrogen atom, a lower heterogenous group, and a lower monovalent hydrocarbon group;

$R^3$  is selected from the group consisting of a monovalent hydrocarbon group, a heterogeneous group, a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted monovalent hydrocarbon group, a substituted heterogeneous group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

$R^4$  is selected from the group consisting of a monovalent hydrocarbon group, a heterogeneous group, a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted monovalent hydrocarbon group, a substituted heterogeneous group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

X is selected from the group consisting of  $-C\equiv C-$ , a covalent bond,  $-CH=C=CH-$ ,  $-CH=CH-$ ,  $-CH=N-$ ,  $-C(O)-$ ,  $-C(O)Y-$ ,  $-(CH_2)_n-$ , wherein n is 2 to 4,  $-CH_2NH-$ ,  $-CH_2S-$ , and  $-CH_2O-$ ;

Y is selected from the group consisting of a sulfur atom, an oxygen atom, and NH; and

Z is selected from the group consisting of a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group.

17. (Withdrawn) The method of claim 16, wherein  $R^1$  is selected from the group consisting of  $CO_2H$ ,  $C(O)NHOH$ ,  $CO_2R^3$ ,  $C(O)NHS(O)_2R^4$ , and tetrazole.

18. (Withdrawn) The method of claim 16, wherein  $R^2$  is a hydrogen atom.

19. (Withdrawn) The method of claim 16, wherein  $R^3$  is selected from the group consisting of methyl, ethyl, and isopropyl.

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20. (Withdrawn) The method of claim 16, wherein  $R^4$  is a phenyl group.

21. (Withdrawn) The method of claim 16, wherein X is a covalent bond and Z is selected from the group consisting of an aromatic ring, a heteroaromatic ring, a substituted aromatic ring, and a substituted heteroaromatic ring.

22. (Withdrawn) The method of claim 16, wherein X is  $-C\equiv C-$ , and Z is a monocyclic aromatic ring.

23. (Withdrawn) The method of claim 16, wherein the composition is administered by a route selected from the group consisting of systemic and topical routes.

24. (Withdrawn) The method of claim 23, wherein the composition is a topical composition in a form selected from the group consisting of solutions, oils, creams, ointments, gels, lotions, shampoos, leave-on and rinse-out hair conditioners, milks, cleansers, moisturizers, sprays, and skin patches.

25. (Withdrawn) The method of claim 23, wherein the composition is a topical composition further comprising B) a carrier, wherein the carrier is selected from the group consisting of water, alcohols, aloe vera gel, allantoin, glycerin, vitamin A and E oils, mineral oil, propylene glycol, dimethyl isosorbide, polypropylene glycol-2 myristyl propionate, and combinations thereof.

26. (Withdrawn) The method of claim 23, wherein the composition further comprises C) an activity enhancer selected from the group consisting of i) a hair growth stimulant, ii) a penetration enhancer, and combinations thereof.

27. (Withdrawn) The method of claim 26, wherein component i) is selected from the group vasodilator, an antiandrogen, a cyclosporin, a cyclosporin analog, an antimicrobial, an anti-inflammatory, a thyroid hormone, a thyroid hormone derivative, and a thyroid hormone analog, a non-selective prostaglandin agonist, a non-selective prostaglandin antagonist, a retinoid, a triterpene, and combinations thereof.

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28. (Withdrawn) The method of claim 26, wherein component ii) is selected from the group consisting of 2-methyl propan-2-ol, propan-2-ol, ethyl-2-hydroxypropanoate, hexan-2,5-diol, polyoxyethylene(2) ethyl ether, di(2-hydroxypropyl) ether, pentan-2,4-diol, acetone, polyoxyethylene(2) methyl ether, 2-hydroxypropionic acid, 2-hydroxyoctanoic acid, propan-1-ol, 1,4-dioxane, tetrahydrofuran, butan-1,4-diol, propylene glycol dipelargonate, polyoxypropylene 15 stearyl ether, octyl alcohol, polyoxyethylene ester of oleyl alcohol, oleyl alcohol, lauryl alcohol, dioctyl adipate, dicapryl adipate, di-isopropyl adipate, di-isopropyl sebacate, dibutyl sebacate, diethyl sebacate, dimethyl sebacate, dioctyl sebacate, dibutyl suberate, dioctyl azelate, dibenzyl sebacate, dibutyl phthalate, dibutyl azelate, ethyl myristate, dimethyl azelate, butyl myristate, dibutyl succinate, didecyl phthalate, decyl oleate, ethyl caproate, ethyl salicylate, isopropyl palmitate, ethyl laurate, 2-ethyl-hexyl pelargonate, isopropyl isostearate, butyl laurate, benzyl benzoate, butyl benzoate, hexyl laurate, ethyl caprate, ethyl caprylate, butyl stearate, benzyl salicylate, 2-hydroxypropanoic acid, 2-hydroxyoctanoic acid, dimethyl sulphoxide, N,N-dimethyl acetamide, N,N-dimethyl formamide, 2-pyrrolidone, 1-methyl-2-pyrrolidone, 5-methyl-2-pyrrolidone, 1,5-dimethyl-2-pyrrolidone, 1-ethyl-2-pyrrolidone, phosphine oxides, sugar esters, tetrahydrofurfural alcohol, urea, diethyl-m-toluamide, 1-dodecylazacycloheptan-2-one, and combinations thereof.

29. (Withdrawn) The method of claim 23, wherein the composition is a topical composition locally administered on the skin once per day.

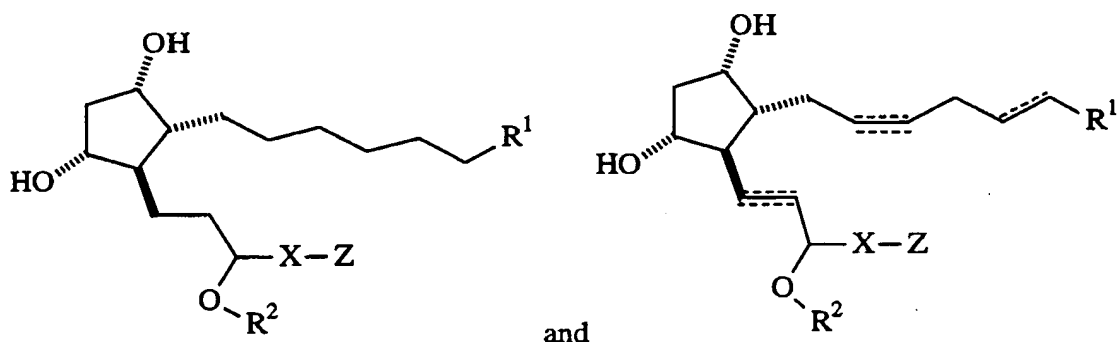
30. (Withdrawn) The method of claim 29, wherein the composition is administered once per day for 6 to 12 weeks.

31. (Withdrawn) A mascara composition comprising:

A) an active ingredient selected from the group consisting of a prostaglandin F analog having a structure selected from the group consisting of

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pharmaceutically acceptable salts and hydrates of the structures above; biohydrolyzable amides, esters, and imides of the structures above; optical isomers, diastereomers, and enantiomers of the structures above; and combinations thereof;

wherein  $R^1$  is selected from the group consisting of  $C(O)OH$ ,  $C(O)NHOH$ ,  $C(O)OR^3$ ,  $CH_2OH$ ,  $S(O)_2R^3$ ,  $C(O)NHR^3$ ,  $C(O)NHS(O)_2R^4$ , tetrazole, a cationic salt moiety, a pharmaceutically acceptable amine or ester comprising 2 to 13 carbon atoms, and a biometabolizable amine or ester comprising 2 to 13 atoms;

$R^2$  is selected from the group consisting of a hydrogen atom, a lower heterogenous group, and a lower monovalent hydrocarbon group;

$R^3$  is selected from the group consisting of a monovalent hydrocarbon group, a heterogeneous group, a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted monovalent hydrocarbon group, a substituted heterogeneous group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

$R^4$  is selected from the group consisting of a monovalent hydrocarbon group, a heterogeneous group, a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted monovalent hydrocarbon group, a substituted heterogeneous group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

X is selected from the group consisting of  $-C\equiv C-$ , a covalent bond,  $-CH=C=CH-$ ,  $-CH=CH-$ ,  $-CH=N-$ ,  $-C(O)-$ ,  $-C(O)Y-$ ,  $-(CH_2)_n-$ , wherein n is 2 to 4,  $-CH_2NH-$ ,  $-CH_2S-$ , and  $-CH_2O-$ ;

Y is selected from the group consisting of an oxygen atom, a sulfur atom, and NH;  
 and

Z is selected from the group consisting of a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted carbocyclic group, a

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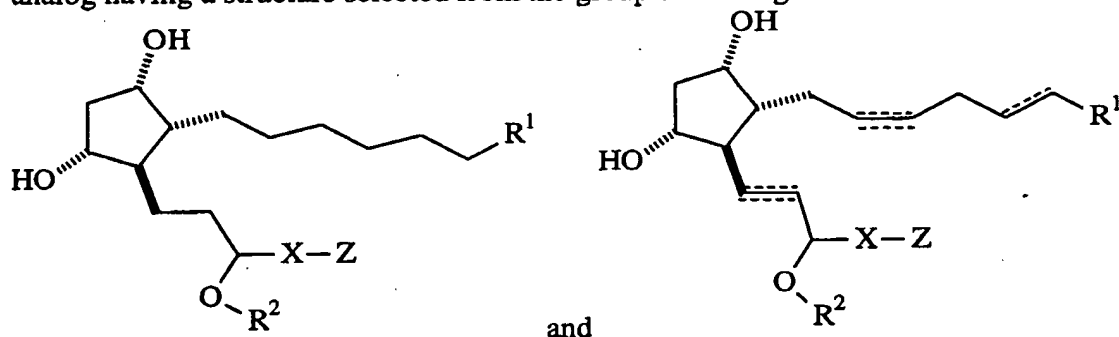
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substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

- dd) a water-insoluble material,
- ee) a water-soluble, film-forming polymer,
- ff) a wax;
- o) a surfactant;
- gg) pigment; and
- s) a solvent.

32. (Withdrawn) A method for darkening and thickening hair comprising applying to growing hair and skin, a composition comprising:

A) an active ingredient selected from the group consisting of a prostaglandin F analog having a structure selected from the group consisting of



pharmaceutically acceptable salts and hydrates of the structures above; biohydrolyzable amides, esters, and imides of the structures above; optical isomers, diastereomers, and enantiomers of the structures above; and combinations thereof;

wherein  $R^1$  is selected from the group consisting of  $C(O)OH$ ,  $C(O)NHOH$ ,  $C(O)OR^3$ ,  $CH_2OH$ ,  $S(O)_2R^3$ ,  $C(O)NHR^3$ ,  $C(O)NHS(O)_2R^4$ , tetrazole, a cationic salt moiety, a pharmaceutically acceptable amine or ester comprising 2 to 13 carbon atoms, and a biometabolizable amine or ester comprising 2 to 13 atoms;

$R^2$  is selected from the group consisting of a hydrogen atom, a lower heterogenous group, and a lower monovalent hydrocarbon group;

$R^3$  is selected from the group consisting of a monovalent hydrocarbon group, a heterogeneous group, a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted monovalent hydrocarbon group, a substituted

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heterogeneous group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

$R^4$  is selected from the group consisting of a monovalent hydrocarbon group, a heterogeneous group, a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted monovalent hydrocarbon group, a substituted heterogeneous group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group;

X is selected from the group consisting of  $-C\equiv C-$ , a covalent bond,  $-CH=C=CH-$ ,  $-CH=CH-$ ,  $-CH=N-$ ,  $-C(O)-$ ,  $-C(O)Y-$ ,  $-(CH_2)_n-$ , wherein n is 2 to 4,  $-CH_2NH-$ ,  $-CH_2S-$ , and  $-CH_2O-$ ;

Y is selected from the group consisting of an oxygen atom, a sulfur atom, and NH;  
and

Z is selected from the group consisting of a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group; and

B) a carrier.

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